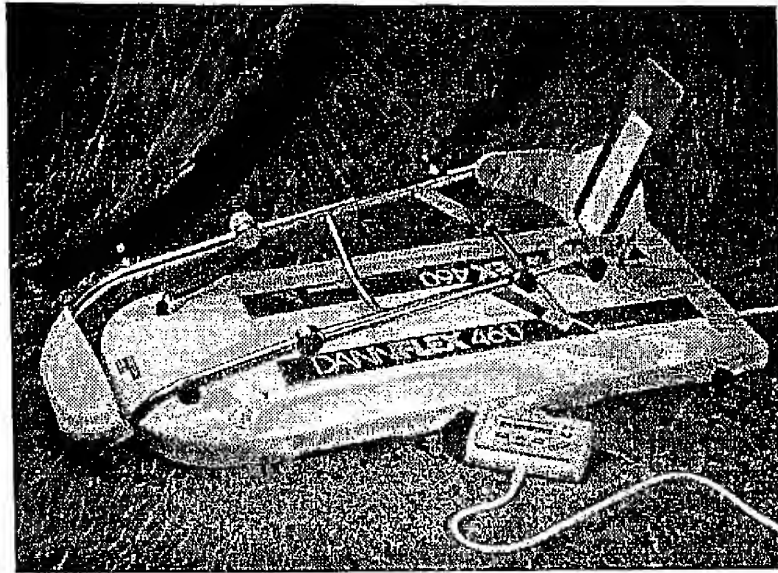




Service Manual



DANNIFLEXTM 460 CPM SYSTEM

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1. Introduction

The Danniflex 460 Continuous Passive Motion (CPM) system is designed for the rehabilitation of the lower limbs. The 460 offers changeable thigh and calf components allowing pediatric usage. The purpose of this manual is to provide maintenance, repair and service instructions for the 460 CPM system. If you have any questions on the servicing of this unit, please call our service department at (800)225-1814 or (614)276-8267.

1.1 CPM Safety Precautions

When using your CPM, to reduce the risk of fire, electric shock and injury to persons, basic safety precautions should always be observed, including the following:

1. Read and understand all instructions.
2. Follow all warnings and instructions marked on the product.
3. Use only Danninger Medical parts for repair and/or replacement.
4. Never use parts from other manufacturer's units with this unit even though they may seem to fit.
5. Never install the wall transformer in wet locations.
6. Never touch uninsulated transformer wires or terminals unless the transformer has been unplugged from the wall outlet.
7. Unplug this product from the wall outlet before cleaning. Do not use liquid cleaners or aerosol cleaners. Use a damp cloth for cleaning.
8. Do not use this product near water.
9. Do not place this product on an unstable cart, stand or table. The product may fall causing serious injury to the patient or damage to the CPM.
10. This product should be operated only from the type of power source indicated on the marking label. If you are not sure of the type of power supply, consult your dealer or local power company.
11. Do not allow anything to rest on the power cord. Do not locate this product where the cord will be abused by persons or equipment moving over or near it.
12. Do not overload wall outlets or use extension cords as this may result in the risk of fire or electric shock.
13. Never push objects of any type into this product through the drive unit casing as they may touch dangerous voltage points or short out parts that could result in a risk of fire or electric shock.
14. To reduce the risk of electric shock, do not disassemble this product, but take it to a qualified serviceman when service or repair work is required. Opening or removing covers may expose you to dangerous voltages or other risks. Incorrect re-assembly can cause electric shock when the unit is subsequently used.
15. If at any time during therapy the patient experiences extreme pain or discomfort, stop therapy and consult their physician.
16. Unplug the product from the wall outlet and refer servicing to qualified personnel under the following conditions:

If the power supply cord is damaged or frayed

- If liquid has been spilled into the product
- If the product has been exposed to rain or water
- If the product has been dropped or the unit casing has been damaged
- If the product exhibits a distinct change in performance
- If the product does not operate normally by following the operating instructions

17. Adjust only those controls that are covered by the operating instructions

1.2 On the Danniflex 460 you will find two areas marked with the "See Accompanying Documents" symbol. These are:



Under the cradle area - This is an area of possible interference. Patients must be advised to keep clear of this area when the CPM is in motion. The unit is designed to force-reverse if an obstruction is under the cradle; however, a patient could experience pain or be injured by the downward pressure of the cradle if they are positioned in such a way that some body part is under the cradle.

At the power switch area - Note that the Danniflex 460 is "on" or in a "standby" mode if the unit is plugged in. To completely disconnect power from the CPM it must be unplugged from the wall outlet.

1.3 Model 460 classifications (regulatory classes defined)

This unit is classified by IEC standards as Class II, Type "B", Category AP.

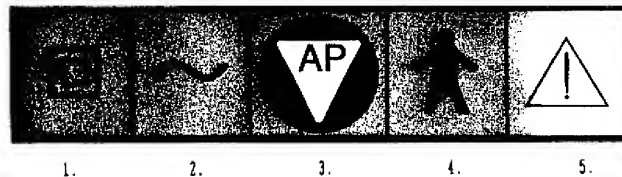
Definitions:

Class II - Equipment in which protection against electric shock does not rely on "basic insulation" only, but in which additional safety precautions such as "double insulation" or "reinforced insulation" are provided, there being no provision for protective earthing or reliance upon installation conditions.

Type "B" - Equipment providing a particular degree of protection against electric shock, particularly regarding allowable "leakage current" and/or reliability of the protective earth connection (if present).

Category AP - Equipment or equipment part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a "flammable anaesthetic mixture with air".

1.4 Symbols and abbreviations used in this manual or on the model 460 are listed below accompanied by their definition.



1. Unit rated Class II
2. Unit requires AC power
3. Unit is classified Category AP
4. Unit rated Type B
5. "See Accompanying Documents"

CPM - Continuous Passive Motion
PCB - Printed Circuit Board
uc - Microcontroller
ROM - Range of Motion
IEC - International Electro-technical Commission

1.5 Getting To Know The Unit

This document assumes a basic knowledge of the Danniflex 460 CPM device operation. If you are unfamiliar with the 460, please read the Operator's Manual before proceeding.

simultaneously.
***Note: Total cycles and hours are non-resettable.

2.4 Maintenance Instruction - Level I

2.4.1 Knobs

2.4.1.1 Removal:

- 1) Approaching the unit from the thigh pivot end, cradle knobs are removed by turning the knobs on the right side of the unit toward you and removed from the left side of the unit by turning the knobs away from you.
- 2) Approaching the unit from the power switch end, the knobs on the bed mount tubes are removed by turning the knob on the right side toward you and removed from the left side by turning the knob away from you.

2.4.1.2 Installation:

- 1) Approaching the unit from the thigh pivot end, cradle knobs are installed by turning the knobs on the right side of the unit away from you and installed on the left side of the unit by turning the knobs toward you.
- 2) Approaching the unit from the power switch end, the knobs on the bed mount tubes are installed by turning the knob on the right side away from you and installed on the left side by turning the knob toward from you.

2.4.2 Kneepot cover

***Note: Plastic rivets may be re-used if not damaged during removal.

2.4.2.1 Removal:

- 1) Push centers of plastic kneepot cover rivets through to center of casting.
- 2) With a pair of diagonal cutters carefully pry out the rivets.
- 3) Pull cover off of kneepot.
- 4) Remove center of kneepot rivet from casting by moving outer thigh tube so they fall out.
- 5) Store all hardware in a safe place for later re-assembly.

2.4.2.2 Installation:

- 1) Make a right angle bend in the kneepot cable insulation. It should be approximately 1/2" from the end of the insulation. This is where the individual wires begin.
- 2) Install this bend in the kneepot cable retention slot in the casting.
- 3) Install the kneepot cover over the casting aligning the cable with the small divot in the cover and in the casting with the holes in the plastic.
- 4) Install the outside of the plastic kneepot rivets into the mounting holes.
- 5) Install the center piece of the plastic rivets into the center of the plastic rivets.
- 6) With a small hammer gently tap the centers of the plastic kneepot rivet flush with the outside of the plastic rivet.

*****CAUTION: Before performing any type of work on this equipment care should be taken to protect persons from any disease which can be transmitted through bodily fluids. Due to the typical environment in which this equipment is used, it may contain bodily fluids not visible from the outside of the unit.

2. Service Level I

2.1 How NOT to void the warranty.

The one-year limited warranty on this product is valid only if NONE of the following incidents have occurred:

- one or both covers removed
- damage by accident
- damage resulting from abuse
- damage resulting from misuse or misapplication
- unauthorized repairs or alterations

2.2 Who this involves and the equipment needed.

Individuals with an average level of mechanical ability should be capable of performing Level I maintenance tasks. You must have available and be proficient in the use of the following tools:

- small punch
- diagonal cutters
- small hammer

2.3 Periodic maintenance schedule for this service level

2.3.1 Recommended care of the CPK

The following list of tasks should be completed before and after each use.

- Use a soft cloth dampened with a mild soap solution or alcohol to gently wipe all exposed surfaces.
- Avoid abrasive cleansers. To disinfect, wipe all exposed surfaces with a solution of 90% water and 10% bleach.
- Ensure that all knobs are in place and usable.
- Ensure that all tubes slide freely as required.
- Check entire unit for any visible evidence of damage such as bent tubes, cracked or broken covers, frayed or damaged wires, etc. If any signs of damage are found the unit should be repaired before subsequent use.
- Check all displays and electronic controls for proper operation.

2.3.2 Normal operations

2.3.2.1 Power-up (starting the unit)

- 1) Remove the power cord from the storage receptacle located on the side of the foot plate bracket.
- 2) Ensure that both the power cord and the pendant cord are uncoiled from the unit.
- 3) Plug unit into appropriate wall socket.
- 4) Turn unit on via the power switch located at the base of the orthosis.

2.3.2.2 Set-Lock

- 1) To change EXTEND, FLEX, SPEED or PAUSE settings, place the PENDANT switch in the SET position.
- 2) To prevent inadvertent changes to the chosen settings, place the PENDANT switch in the LOCK position.

2.3.2.3 Stim

- 1) Set the desired PAUSE interval.
- 2) Connect a muscle stimulation device to the NMES trigger jack located at the base of the orthosis.
- 3) Refer to the muscle stimulator instruction manual for proper set-up.

2.3.2.4 Bookkeeping

- 1) To check the number of user cycles since the last reset, depress HOUR/CYCLE button. ("User Cycles and Hours" will appear in the display window.)
- 2) To reset the User Cycle and Hours, depress EXTEND, SPEED, HOURS/CYCLES, and FLEX simultaneously. ("HRS & CYC RESET" will appear in the display window.)
- 3) To check the total cycles since the unit was manufactured, depress EXTEND and HOURS/CYCLES simultaneously.
- 4) To check the total hours since the unit was manufactured, depress FLEX and HOURS/CYCLES

3. Service Level II

3.1 Who this involves and the equipment needed.

In order to perform Level II maintenance an individual must be above average in their mechanical ability and be able to solder and de-solder. You must have available and be proficient in the use of the following tools:

- medium sized phillips head screwdriver
- thin blade standard screwdriver
- small hammer
- diagonal cutters
- 3/16" hex key
- small punch
- exacto-knife
- soldering iron
- de-soldering equipment
- adjustable wrench
- pliers

You may also need the following disposable items:

ASSURE Loctite #242

ASSURE Loctite #42540

***Note: Do not use any other type of adhesive or Loctite. They will destroy the plastic covers.

ty-wraps similar to the ones used in the unit

solder

DMT Part #12587 Pendant Back Cover Label

3.2 Periodic maintenance schedule for this service level

3.2.1 Recommended care of the CPM

In addition to the items listed in section 2.3.1 which are done before and after each usage, the following list of tasks should be performed at the end of the first year of use and every six months thereafter:

- 1) Check all mechanical pivot and linkage points for smooth operation and secure mechanical connection. Make sure all screws, rivets and pivot pins are secure.
- 2) Remove bottom cover and inspect all motor and ballscrew linkages and bearings for smooth operation and for excess wear. The ballscrew should have a thin film of light lubricant along its length.
- 3) Replace any missing or worn washers, spacers, bearings or bushings.
- 4) Check all wiring, wiring connections and circuit boards for secure mounting and clearance from moving mechanical components.
- 5) If there are any signs of improper operation the CPM should be repaired by a qualified service technician.

3.3 Maintenance instruction level II

3.3.1 Bottom Cover

Disposable items needed for this task:

ASSURE Loctite #42540

3.3.1.1 Removal:

***Note: Do not cut the heads off the plastic fasteners. Doing this will render them useless. Undamaged fasteners can be used for re-assembly.

- 1) Locate the unit's handle.
- 2) Remove the two phillips head screws on each end of the handle.
- 3) Remove the handle.
- 4) Remove all plastic fasteners from around the cover using the following method:
 - a) Using a thin blade standard screwdriver, insert the tip between the fasteners male half and female half.
 - b) Carefully rotate the screwdriver enough to pull the fastener apart.
 - c) Remove the fastener's female half from each hole.
- 5) Carefully remove the bottom cover from under the unit.
- 6) Store all hardware in a safe place for later use.

3.3.1.2 Installation

- 1) Carefully place the bottom cover on the base.
- 2) Align the bottom cover's holes with the holes in the top cover.
- 3) Insert the female half of the plastic fastener into the holes surrounding the cover.
- 4) Insert one male half into each of the female halves.
- 5) With a small hammer gently seat the two sections together.
- 6) Locate the two handle holes.
- 7) Apply one drop of ASSURE Loctite #42540 on each phillips head screw.
- 8) Place the handle assembly and screws into their appropriate holes.
- 9) Using a phillips screwdriver, tighten the handle screws.

***Note: Do not over tighten. Doing so will strip the threads in the base.

3.3.2 Cradle

Disposable items needed for this task:

ASSURE Loctite #242

ASSURE Loctite #42540

(1) ty-wrap

3.3.2.1 Removal:

- 1) Remove the bottom cover (refer to section 3.3.1.1).
- 2) Remove kneepot cable from the connector on the main PC board.
- 3) Using a pair of diagonal cutters, remove the ty-wrap that holds the kneepot cable secure to the base.
- 4) Remove the kneepot cable strain relief from the top cover by removing the underside nut.
- 5) Slide strain relief nut and rubber washer off the cable end.
- 6) Pull kneepot cable gently through the hole in the top cover.
- 7) Remove both 3/16" cradle pivot allen bolts from the U-bracket assembly. While removing the bolts from their holes, apply a small tilt and pull the bolt straight out. This should also remove the pivot's sleeve.
- 8) Lift the cradle through the top cover.
- 9) Loosen both cradle/thigh tube adjuster knobs and remove the cradle.
- 10) Store all hardware for later re-assembly.

3.3.2.2 Installation:

- 1) Gently spread rubber track seals and slide cradle struts between the track seals through the top cover.
- 2) Slide cradle struts into drive pivot plates. This secures the cradle to the U-bracket assembly.
- 3) Place both pivot sleeves into their proper locations.
- 4) Apply one drop of ASSURE loctite #242 on the threads of each cradle pivot allen bolt.
- 5) Using a 3/16" hex key, install the two allen bolts into the U-bracket assembly.
- 6) Slide the kneepot cable through both the top cover and the base.
- 7) Slide the rubber washer first onto the kneepot cable, then the strain relief nut.
- 8) Tighten the nut 1/4 turn past finger tight.
- 9) Install the kneepot cable connector onto the PC board connector pins 1,2,3.
- 10) Ty-wrap the kneepot cable to the base frame.
- 11) Install the bottom cover (refer to section 3.3.1.2).

3.3.3 Top cover

Disposable items needed for this task:

ASSURE Loctite #242

ASSURE Loctite #42540

(1) ty-wrap

3.3.3.1 Removal:

- 1) Remove bottom cover (refer to section 3.3.1.1).
- 2) Remove cradle (refer to section 3.3.2.1).
- 3) Carefully remove the top cover.
- 4) Store all hardware for later re-assembly.

3.3.3.2 Installation:

- 1) Place top cover on top of CPK base frame.
- 2) Install cradle (refer to section 3.3.2.2).
- 3) Install bottom cover (refer to section 3.3.1.2).

3.3.4 Kneepot cable

Disposable items needed for this task:

ASSURE Loctite #42540

solder

(1) ty-wrap

3.3.4.1 Removal:

- 1) Remove bottom cover (refer to section 3.3.1.1).
- 2) Remove kneepot cover (refer to section 2.4.2.1).
- 3) Remove kneepot cable connector from connector on main PC board.
- 4) Use diagonal cutters to remove all ty-wraps from kneepot cable.
- 5) Remove connector end from kneepot cable (With a thin tip screwdriver or exacto-knife remove the connector's pins. Push the tabs on the metal pins toward the connector housing. Push the pins out of the connector housing. The metal tabs are accessible through the slots on the side of the connector.)
- 6) Remove strain relief from top cover by removing the nut on the bottom side of the top cover.
- 7) Slide bottom strain relief nut off of cable end.
- 8) Slide rubber washer off of cable end.
- 9) Pull cable through cover.
- 10) De-solder cable from terminals on kneepot.
- 11) Remove top section of strain relief by loosening top nut and sliding cable through strain relief.

***Note: Caution must be taken when pulling the kneepot cable ends through the connector to insure that you do not bend the fragile ends.

- 12) Store all hardware in a safe place for later re-assembly.

3.3.4.2 Installation:

- 1) Position the top half of the strain relief on longest straight end of kneepot cable so the domed end points toward the coils.
- 2) Move strain relief to coils.
- 3) Tighten the top nut 1/4 turn past finger tight.
- 4) Strip off enough insulation to wrap one complete turn around kneepot cables.
- 5) Wrap wires one and one-quarter turns around kneepot terminals and solder as follows:
 pin #1 - Blue - Grd
 pin #2 - Orange - Wiper
 pin #3 - Yellow - +5V
- 6) Install kneepot cover (refer to section 2.4.2.2).
- 7) Carefully put kneepot cable through top cover.
- 8) Put rubber washer on kneepot cable.
- 9) Install bottom strain relief nut on kneepot cable.
- 10) Tighten strain relief bottom nut 1/4 turn past finger tight.
- 11) Install kneepot cable connector on cable end.

***Note: Kneepot cable connector pins are:

- pin #1 - Blue
- pin #2 - Orange
- pin #3 - Yellow

- 12) Install kneepot cable connector onto main PC board connector ** pins 1,2,3.
- 13) Gather excess cable and secure to front of base frame with (1) ty-wrap.
- 14) Install bottom cover (refer to section 3.3.1.2).

3.3.5 Motor

Disposable items needed for this task:

ASSURE Loctite #42540

3.3.5.1 Removal:

- 1) Remove bottom cover (refer to section 3.3.1.1).
- 2) Remove motor connector from main PC board and pull connector through hole in base frame.
- 3) Remove the four rubber mount nuts from inside the bearing bracket assembly.
- 4) Take the motor out of the assembly, making sure that you do not lose the internal tooth star washers. (two per mount)
- 5) Remove the rubber coupling from either the motor or bearing bracket assembly.

3.3.5.2 Installation:

- 1) Insert the rubber coupling into the bearing bracket assembly.
- 2) Position the motor in the base. The motor plate holes will align with the rubber mounts and rubber female coupling will align with the motor male coupling.
- 3) Place two internal tooth stars washer between each of the rubber mounts and the motor plate.
- 4) Insert the four motor mount screws and tighten. Be careful not to twist the rubber mounts when tightening the screws.
- 5) Install the bottom cover (refer to section 3.3.1.2)

3.3.6 Transformer

Disposable items needed for this task:

ASSURE Loctite #42540

3.3.6.1 Removal:

- 1) Remove bottom cover (refer to section 3.3.1.1).
- 2) Disconnect transformer cable connection from the power switch.
- 3) Carefully pull transformer wires from the unit.
- 4) Store all hardware in a safe place for re-assembly.

3.3.6.2 Installation:

- 1) Measure from the end of the cable 3" toward the wall transformer. It is measured where the outside insulation of the cable ends.
- 2) Make a sharp 90 degree bend.
- 3) Install the right angle strain relief at this bend so the insertion end of the strain relief is pointed toward the power switch connectors.
- 4) Insert wall transformer cable through base frame.
- 5) Using a pair of pliers squeeze both halves of the strain relief together.
- 6) Press in strain relief.
- 7) Re-connect and/or solder wires according to color codes.
- 8) Install ty-wraps as needed.
- 9) Install bottom cover (refer to section 3.3.1.2)

3.3.7 Ballscrew

Disposable items needed for this task:

ASSURE Loctite #42540

(2) ty-wraps

3.3.7.1 Removal:

- 1) Remove bottom cover (refer to section 3.3.1.1)
- 2) Disconnect the motor by removing the 4 nuts from the bearing bracket.
- 3) Displace the entire motor assembly.
- 4) Loosen the ballscrew nut.
- 5) Loosen the appropriate knobs and detach the cradle from the thigh assembly.
- 6) Slide the cradle and the U-bracket assembly all the way to the full extension end.
- 7) Being careful to hold the bearing end of the ballscrew in place, lift the bearing bracket and ballscrew out of the thigh end of the unit by guiding it toward the side of the frame while lifting.
- 8) Store all hardware for later assembly.

3.3.7.2 Installation:

- 1) Check to make sure that the plastic bearing for the ballscrew is located in its proper position then carefully place the ballscrew free end into the plastic bearing.

- 2) Slide the bearing bracket end down into place. The four holes in the assembly should align with the frame holes.
- 3) Place the rubber mounts into the frame holes and through the bracket assembly, making sure that the washers are on the threaded side of the mounts.
- 4) Secure the ballscrew in place by screwing the mount nuts on the inside of the bracket assembly on the end of each mount and tightening.
- 5) Tighten the ballscrew nut.
- 6) Re-install the motor assembly.
- 7) Install the bottom cover (refer to section 3.3.1.2)

3.3.8 Pendant Cable

Disposable items needed for this task:

ASSURE Loctite #42540

(5) ty-wraps

DMT Part #12587

3.3.8.1 Removal:

- 1) Remove bottom cover (refer to section 3.3.1.1).
- 2) Cut ty-wraps from the entire length of the pendant cable being careful not to damage the ribbon cable.
- 3) Pull the cable connector off the board mounted connector.
- 4) Remove the strain relief and pull the cord through the base.
- 5) Remove back cover label from pendant.
- 6) Using a medium sized phillips head screw driver, remove the four screws from the back of the pendant.
- 7) Remove the back of the pendant housing.
- 8) Carefully pull the pendant board straight away from the front half of the pendant housing.
- 9) Cut the ty-wrap which holds the cable flat to the board.
- 10) Carefully slide cable connector from the board mounted connector pins.

3.3.8.2 Installation

- 1) Carefully slide cable connector onto the pendant board connector.
- 2) Position the cable so the shielded cable comes up over the edge of the pendant board. Ty-wrap the cable in place and flat to the board.
- 3) Guiding the pins from the pendant control board into the connector on the main pendant board carefully squeeze the two boards together until the connector is well seated.
- 4) Place the back half of the pendant housing in position.
- 5) Insert the four phillips head screws and tighten.
- 6) Replace the back cover label.
- 7) Slide the board end of the cable through the opening in the base.
- 8) Re-position the strain relief.
- 9) Connect the cable to the board mounted connector.
- 10) Install the bottom cover (refer to section 3.3.1.2).

3.3.9 Error Codes

3.3.9.1 Error codes in general

Errors are handled on a case by case basis. Detection of some errors stops the CPM. At that time it will display an error code. It then burns the associated error code into the EE_ERROR byte in EEPROM. For other lesser errors the only action taken is to burn the code into EEPROM. The specific actions of each error are detailed in the following text. Whenever the EE_ERROR byte in EEPROM contains a non-zero value the unit will display:

*****WAIT*****

on power-up for approximately one second. This indicates that an error was detected at some time. After the "*****WAIT*****" display you will see either the normal screen or a fatal error code. The EE_ERROR byte is reset by getting into the calibration mode. Refer to section 4.3.6 for further instructions.

3.3.9.2 Details of specific error codes

[E1]: KNEE PIVOT ANGLE CALIBRATION ERROR

Error Action: This error prevents the CPM from entering the run mode.

Display: CALIBRATE [E1]

Cause: An invalid knee pivot angle calibration is indicated by bit 0 of EE_CAL_STATUS being 0

Corrective Action: Re-calibrate the unit (refer to section 4.3.6).

[E2]: MECHANICAL LIMIT CHECK OR FORCE CHECK VALIDATION ERROR

Error Action: See Display

Display: CALIBRATE [-]

Cause: The extension limit check, the flexion limit check or the force check was not fully executed. This action occurs when the unit is calibrated.

Corrective Action: Re-calibrate the unit (refer to section 4.3.6).

[E3]: EE EXT CAL OR EE FLEX CAL EEPROM VARIABLE ERROR

Error Action: This error prevents the CPM from entering the run mode.

Display: CALIBRATE [E3]

Cause: On power-up the microcontroller checks the values of EE_EXT_CAL and EE_FLEX_CAL. Limits are imposed on the value of these variables at calibration. If the values read from EEPROM are not within these limits the variable is assumed to be corrupted and an error is generated.

Corrective action: Re-calibrate the unit (refer to section 4.3.6).

[E4]: SOFTWARE TIMER ERROR

Error Action: This error causes the microcontroller to burn 4 in the EE_ERROR EEPROM.

Display: *****WAIT*****

Cause: A software variable called Timer Overflow Interrupt Count (TOI Count) is incremented every time the timer overflows. After the value of the TOI Count becomes greater than 2746 the timer value in EEPROM is incremented and the 2746 is subtracted from TOI Count. If for some reason this process fails and TOI Count becomes greater than 32000 Error 4 is generated.

Corrective Action: Contact Danninger Medical's Customer Service Department and inform them of the error. Either the microcontroller or the main PCB may need to be replaced.

[E5]: MOTOR SPEED MEASUREMENT ERROR

Error Action: This error causes the microcontroller to burn 5 in the EE_ERROR EEPROM and causes the CPM to stop.

Display: *****WAIT*****

Cause: With every revolution of the motor the MC33039 detects when the sensor in the motor makes a transition. That is when the sensor goes from high to low or low to high. It generates a pulse of fixed width. The microcontroller measures the speed of the motor by counting the number of pulses that occur in one timer overflow period. This happens in 131 seconds. When the unit runs too fast (over 230 RPM) the time between sensor transitions becomes less than the pulse width. The microcontroller counts 0 pulses therefore the speed measured=0 even though the motor is revolving.

Corrective Action: Troubleshoot PCB. MC33039 OSC Resistor-Capacitor combination may be out of tolerance. There can be excessive noise on the Hall effect sensor inputs, a bad MC33039, a bad microcontroller, etc. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E6]: EEPROM INITIALIZATION ERROR

Error Action: This error prevents the CPM from entering the run mode.

Display: EEPROM ERR [E6]

Cause: During initial calibration certain variables in EEPROM are initialized. If there is some problem and one of these variables cannot be written to EEPROM, error 6 is generated.

Corrective Action: Perform the bulk erase procedure. If the problem recurs replace the microcontroller or the PCB.

[E7]: CYCLE COUNTER ERROR

Error Action: This error causes the microcontroller to burn 7 in the EE_ERROR EEPROM.

Display: *****WAIT*****

Cause: Every time the unit pauses in extension a variable in the software called cycles since save is incremented. Every six minutes of operation the timer is incremented and the total cycle count is increased by the cycles since save, after which cycles since save is zeroed. If this process goes awry and cycles since save becomes greater than 500 error 7 is generated.

Corrective Action: Contact Danninger Medical's Customer Service Department and inform them of the error. Either the microcontroller or the main PCB may need to be replaced.

[E8]: MOTOR SPEED ERROR

Error Action: This error causes the microcontroller to burn 8 in the EE_ERROR EEPROM and causes the CPM to stop.

Display: *****WAIT*****

Cause: The maximum CPM rpm is less than 200. If the speed measured is greater than 254 counts in one timer overflow (roughly 500rpm) then error 8 is generated.

Corrective Action: Troubleshoot PCB. MC33039 OSC Resistor-Capacitor combination may be out of tolerance. There can be excessive noise on the Hall effect sensor inputs, a bad MC33039, a bad microcontroller, etc. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E9]: START/STOP ERROR

Error Action: This error causes the microcontroller to burn 9 in the EE_ERROR EEPROM and causes the CPM to stop.

Display: *****WAIT*****

Cause: The microcontroller has detected that the START/STOP key was depressed for more than 16.4 seconds. The START/STOP on the main or auxiliary pendant may have been depressed for that period. The PCC (Patient Control Cord) may have an open circuit. The main pendant may have a short circuit. It is normally open.

Corrective Action: Troubleshoot the pendants and the main PCB. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E10]: KNEEPT WIPER VOLTAGE TOO LOW

Error Action: This error causes the microcontroller to burn 10 in the EE_ERROR EEPROM and causes the CPM to stop.

Display: ANGLE ERROR [E10]

Cause: The kneepot wiper or +8v may have an open. The main PCB may have a problem.

Corrective Action: Examine the kneepot, the kneepot cable and kneepot connector for possible opens and troubleshoot the main PCB. Perform the extension limit check in the calibration mode to assure that the cradle is not traveling outside the kneepot's voltage range. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E11]: KNEEPT WIPER VOLTAGE TOO HIGH

Error Action: This error causes the microcontroller to burn 11 in the EE_ERROR EEPROM and causes the unit to stop.

Display: ANGLE ERROR [E11]

Cause: The problem may be in the main PCB or the kneepot ground may have an open.

Corrective Action: Examine the kneepot, the kneepot cable and kneepot connector for possible opens and troubleshoot the main PCB. Perform the extension limit check in the calibration mode to assure that the cradle is not traveling outside the kneepot's voltage range. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E12]: not used in the Model 460

[E13]: EEPROM VARIABLE ALLOCATION ERROR

Error Action: This causes the microcontroller to burn 13 in the EE_ERROR EEPROM.

Display: *****WAIT*****

Cause: Each variable, in software, has a predetermined amount of EEPROM dedicated to it. The reason being that each byte of EEPROM can be written to only a finite number of times. Upon copying a variable to EEPROM the microcontroller checks that the copy matches the original. If it does not match it goes on to the next byte of EEPROM and tries to write it again. Eventually there may come a time when the variable runs out of the EEPROM that was allocated for it. This generates an error 13.

Corrective Action: Contact Danninger Medical's Customer Service Department and inform them of the error. Either the microcontroller or the main PCB may need to be replaced. (There is enough EEPROM allocated for each variable to last for more than a decade of constant use.)

[E14]: EEPROM POINTER ALLOCATION ERROR

Error Action: This causes the microcontroller to burn 14 in the EE_ERROR EEPROM.

Display: *****WAIT*****

Cause: Each variable, in software, has a predetermined amount of EEPROM dedicated to it. The reason being that each byte of EEPROM can be written to only a finite number of times. Upon copying a variable to EEPROM the microcontroller checks that the copy matches the original. If it does not match an "EEPROM pointer" byte is incremented so the microcontroller is directed to the next byte of EEPROM. It proceeds to write the variable again. However, if the EEPROM pointer, a byte of EEPROM, cannot be incremented, an error 14 is generated. The variable cannot be written to the EEPROM correctly.

Cause: Contact Danninger Medical's Customer Service Department. Either the microcontroller or the main PCB may need to be replaced.

Corrective Action:

[E15]: KNEEPTOT WIPER VOLTAGE NOT CHANGING QUICKLY ENOUGH

Error Action: This causes the microcontroller to burn 15 in the EE_ERROR EEPROM and causes the CPM to stop.

Display: *****WAIT*****

Cause: If the CPM is in the run mode and the A/D converter reading doesn't change by more than two counts in a short, pre-determined amount of time, an error 15 is generated. The problem could be due to a faulty kneepot or kneepot cable.

Corrective Action: Check for a faulty kneepot or kneepot cable. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E16]: CONFIGURATION ERROR

Error Action: This error prevents the CPM from entering the run mode.

Display: EEPROM ERR [E16]

Cause: The CONFIG register is latched on power-up from a CONFIG byte in EEPROM located at the same address. The CONFIG register configures the microcontroller. The EEPROM CONFIG is burned each time the microcontroller is put through calibration. If for some reason the CONFIG is not equal to the correct value, an error 16 is generated.

Corrective Action: Reset EE_ERROR byte by performing the calibration routine (refer to section 4.3.6).

If the problem persists the main PCB may need to be replaced.

[E17]: TOO MANY FORCE REVERSALS

Error Action: This error causes the microcontroller to burn 17 in the EE_ERROR EEPROM and causes the CPM to stop.

Display: *****WAIT*****

Cause: If the unit has seven force reversals in a 30 second period an error 17 will be generated.

Corrective Action: With the unit traveling, look for binding in the unit. Reset EE_ERROR byte by entering the calibration routine (refer to section 4.3.6).

[E18]: INVALID EE MOTOR TYPE

Error Action: This error causes the CPM to exit the run mode.

Display: CALIBRATE [E18]

Cause: Calibration includes a motor type selection. If the EE_MOTOR_TYPE is found to contain something other than the correct selection an error 18 is generated.

Corrective Action: In the calibration mode re-select the motor type. If the error persists, contact Danninger Medical's Customer Service Department.

[E19]: INVALID EE MODEL TYPE

Error Action: This error causes the CPM to exit the run mode.

Display: CALIBRATE [E19]

Cause: Calibration includes a model type selection. If the EE_MODEL_TYPE is found to contain something other than the correct selection an error 19 is generated.

Corrective Action: In the calibration mode re-select the model type. If the error persists, contact Danninger Medical's Customer Service Department.

4. Service Level III

4.1 Who this involves and the equipment needed.

In order to perform Level III maintenance an individual must be highly skilled in both mechanical and electrical repair. You must have available and be proficient in the use of the following tools:

- 460 Angle Fixture (goniometer)
- .1 center jumper (DMT P/N 13412)
- medium sized phillips head screwdriver
- thin blade standard screwdriver
- small hammer
- diagonal cutters
- 3/16" hex key
- small punch
- exacto-knife
- soldering iron
- de-soldering equipment
- adjustable wrench
- pliers

You may also need the following disposable items:

- ASSURE Loctite #242
- ASSURE Loctite #42540
- ***Note: Do not use any other type of adhesive or Loctite. They will destroy the plastic covers.
- ty-wraps similar to the ones used in the unit
- solder
- DMT Part #12587 Pendant Back Cover Label

4.2 Periodic maintenance schedule for this service level

4.2.1 Recommended care of the CPM

In addition to the items listed in section 2.3.1 which are done before and after each usage , and the items listed in section 3.2.1 which should be performed at the end of the first year of use and every six months thereafter, persons performing Level III maintenance should also perform a calibration check while doing the Level II scheduled maintenance. Check angle and speed calibration per product specification. Re-calibrate all parameters which do not comply with specifications.

4.3 Maintenance instruction level III

4.3.1 Main Printed circuit board

Disposable items needed for this task:

ASSURE Loctite #42540

4.3.1.1 Removal

- 1) Remove bottom cover (refer to section 3.3.1.1).
- 2) Remove all connectors from main PCB.
- 3) Gently push the PCB toward the top cover until the nylon standoff is disengaged from the board.
- 4) Store all hardware in a safe place for later assembly.

4.3.1.2 Installation:

- 1) Position the main PCB so all the connectors on the board are facing the foot end of the CPM.
- 2) Place the main PCB above the nylon standoffs.
- 3) While guiding the nylon standoffs into the mounting holes, place the PCB on them.
- 4) Gently pull main PCB toward bottom of base frame so the PCB seats firmly against the stopping pad on the nylon standoffs.
- 5) Install the connectors into main PCB.

***Note: Cable connectors are installed on the following PCB connectors:

- Pendant cord - J2
- Kneepot Cable - J4-1,2,3
- Power switch cord - J4-4,5
- Motor cord - J5

- 6) Install bottom cover (refer to section 3.3.1.2)
- 4.3.2 Pendant Printed Circuit Board
- Disposable items needed for this task:
- DMT Part #12587
- (1) ty-wrap
- 4.3.2.1 Removal:
- 1) Remove back cover label from pendant.
 - 2) Using a medium sized phillips head screw driver, remove the four screws from the back of the pendant.
 - 3) Remove the back of the pendant housing.
 - 4) Carefully pull the pendant board straight away from the front half of the pendant housing.
 - 5) Cut the ty-wrap which holds the cable flat to the board.
 - 6) Carefully slide cable connector from the board mounted connector pins.
 - 7) Lift the board out of the pendant housing.
- 4.3.2.2 Installation:
- 1) Slide the cable connector on the board mounted connector pins.
 - 2) Carefully position the board in the front half of the pendant housing.
 - 3) Gently push the cable into place in the cutout of the housing and ty-wrap the cable flat to the board.
 - 4) Position the back half of the pendant housing making sure that the cable is not pinched between the two halves.
 - 5) Insert four phillips head screws in the holes on the back of the pendant and tighten.
 - 6) Place back cover label on back side of pendant housing.
- 4.3.3 LCD Module
- Disposable items needed for this task:
- DMT Part #12587
- solder
- 4.3.3.1 Removal:
- 1) Remove back cover label from pendant.
 - 2) Using a medium sized phillips head screw driver, remove the four screws from the back of the pendant.
 - 3) Remove the back of the pendant housing.
 - 4) Carefully pull the pendant board straight away from the front half of the pendant housing.
 - 5) Carefully de-solder the LCD Module pins.
 - 6) Remove the screws, nut and standoffs from the board.
 - 7) Lift the module from the main pendant board.
- 4.3.3.2 Installation:
- 1) Place the LCD Module so the board mounted pins on the main pendant board pass through the holes of the LCD Module board.
 - 2) Re-install the screws, nuts and standoffs on the board.
 - 3) Solder all pins being careful not to create solder bridges between pins.
 - 4) Carefully position the main pendant board in the front half of the pendant housing.
 - 5) Gently push the cable into place in the cutout of the housing.
 - 6) Position the back half of the pendant housing making sure that the cable is not pinched between the two halves.
 - 5) Insert the four phillips head screws in the holes on the back of the pendant and tighten.
 - 6) Place back cover label on back side of pendant housing.
- 4.3.4 Bezel or Rubber Keypad
- Disposable items needed for this task:
- DMT Part #12587
- 4.3.4.1 Removal:
- 1) Remove back cover label from pendant.
 - 2) Using a medium sized phillips head screw driver, remove the four screws from the back of the pendant.
 - 3) Remove the back of the pendant housing.
 - 4) Carefully pull the pendant board straight away from the front half of the pendant housing.
 - 5) Lift the board out of the pendant housing.

- 6) Lift the LCD window out of the front half of the pendant and sit it aside where it will not be damaged.
- 7) Using a 1/4" nut driver remove the four locknuts from the inside of the front half.
- 8) Carefully lift the pendant housing away from the front bezel.
- 9) Lift out the pendant control board and the keypad is exposed.

4.3.4.2 Installation:

- 1) Gently press keypad into position inside the bezel checking to be sure that the locator pins have come through the pad.
- 2) Position the pendant control board so that the locator pins also pass through the appropriate holes in the board.
- 3) Place the front half of the pendant housing on top of the bezel/control board assembly and secure with four locknuts.
- 4) Place the LCD window into the opening, being sure that the printing is readable from the front of the pendant.
- 5) Carefully position the main pendant board in the front half of the pendant housing.
- 6) Gently push the cable into place in the cutout of the housing.
- 7) Position the back half of the pendant housing making sure that the cable is not pinched between the two halves.
- 8) Insert the four phillips head screws in the holes on the back of the pendant and tighten.
- 9) Place back cover label on back side of pendant housing.

4.3.5 Fuse

Disposable items needed for this task:

ASSURE Loctite #42540

solder

4.3.5.1 Removal:

- 1) Remove the bottom cover (refer to section 3.3.1.1).
- 2) De-solder the fuse from the main PCB.

4.3.5.2 Installation:

- 1) Form leads as necessary and solder a new fuse to the main PCB.
- 2) Install the bottom cover (refer to section 3.3.1.2).

4.3.6 Calibration

4.3.6.1 Procedures

- 1) Turn off CPM
- 2) Remove bottom cover (refer to section 3.3.1.1).
- 3) Lay the unit on its side.
- 4) Make sure all connectors are connected.
- 5) Jumper J1-5 and J1-6 ***Note: PCB is marked "CTE" which stands for "Cal Test Enable"
- 6) Turn on CPM
- 7) The microcontroller will display the following:
MODEL = 460 or MODEL = 500
- 8) Depress the Up/Down arrows to change to MODEL = 460 if necessary
- 9) Depress the Start/Stop button
 - a) If this is the PCB's first calibration it will initialize the timer, cycles and variables. If for some reason the microcontroller cannot initialize a variable the pendant will display:
EEPROM ERR [E6]
 - b) Check the EE_ERROR byte. Many error conditions are programmed to write their corresponding error code to this byte when they are detected. If EE_ERROR does not equal zero the pendant will display the error code, for example:
[E10] ,<- TO ZERO
would indicate that the last error generated by the CPM was E10. You would find in referring to section 3.3.9 Error Codes, that E10 indicates either an open in the kneepot wiper or kneepot 8V wire. If the EE_ERROR is zero, indicating no errors, the microcontroller will skip the above display.

- c) To reset the EE_ERROR to zero press the Start/Stop button.
 d) New error codes overwrite old error codes.
- 10) Check the EE_TEST_STATUS byte. When the main PCB is tested on the DMT P/N 13385 Functional Test Fixture any detected errors are displayed and a "1" is burned into the EE_TEST_STATUS byte. (Errors can be generated by out of tolerance components, etc...) If no errors were detected the functional test fixture sets EE_TEST_STATUS = 255. When a unit with no errors is later calibrated the "TEST STATUS" display is skipped. If the unit being calibrated has a non-zero EE_TEST_STATUS, then you will see the following display:
- TEST STATUS = NN
- where NN is the error code.

If NN = 255 the PCB has not been tested upon the test fixture P/N 13385.

- 11) Set extension cal point. At this point the display should show:

ext[40-50] NN 0°

where NN is the kneepot voltage reading from the microcontroller's on-board 8 bit A/D converter. Remove the cradle from the thigh assembly and attach goniometer. Position the cradle at zero degrees. If the kneepot has not been pressed into the cradle it should be adjusted so that $39 < NN < 51$ and pressed in. After the kneepot has been pressed into position, or if the kneepot was already pressed in, NN should be re-checked to assure that it is greater than 39 and less than 51 and then the EXTENSION key is pressed. Pressing EXTENSION burns NN into the EE_EXT_CAL byte in EEPROM and zeros the EE_CAL_STATUS byte. If you press EXTENSION and NN is out of range the display will show

see manual

- 12) Set flexion cal point. At this point the display should show:

flx[170-190] NN 90°

where NN again shows the kneepot voltage reading of the microcontroller's on-board A/D converter. The 460 angle fixture should now be moved to the 90 degree position. If step 10 was performed correctly the value of NN will be between 170-190. Check that this is true and if so press the FLEXION button. Pressing FLEXION burns NN into the EE_FLEX_CAL byte in EEPROM and sets EE_CAL_STATUS bit 0. If you press FLEXION and NN is out of range the display will show:

see manual

- 13) Check extension limit. It is important to protect the patient against all types of CPM failures. In particular, kneepot voltages which are out of the standard range (caused by opens in the kneepot circuit) should stop the unit. Towards this end the microcontroller needs to be able to tell the difference between a carriage at the extension or flexion mechanical limit and an open kneepot wire. The display should show:

EXT LIMIT CK NN

Move the thigh pivot tube to the extension limit and press EXTENSION. If $(10 \leq NN \leq 36)$ the microcontroller will set bit 1 of EE_CAL_STATUS and go on to the next screen. If not the unit will display:

see manual

- 14) Check flexion limit. For the same reasons we check the flexion limit. The display should show:

FLX LIMIT CK NN

Move the carriage to the flexion limit. If $(170 \leq NN \leq 250)$ the unit will set bit 2 of EE_CAL_STATUS and go on to the next screen. If not the unit will display: *press flex*

see manual

- 15) Force check. Attach cradle to thigh assembly. The force/speed curve of a brushless motor is consistent from unit to unit and constant over time. Thus we do not calibrate force but at the same time we need to check that the unit does not bind anywhere in its range. In order to pass the force check the unit must run without binding or being stopped from 110 to -5 degrees or vice versa. The display should now show:

FORCE CHECK <-

Depress the START/STOP key on the pendant and the CPM will enter the force check run mode and display:

AAA FOR[SSS]= NNN

where AAA=Kneepot angle in degrees, SSS= Force reversal setpoint, NNN= Measured force
If NNN > SSS for about one second the unit will stop and the display will show:

BINDING<-

If you now press the pendant START/STOP the unit will again run in the force check mode. You may wish to enter the run-in mode. To do this hold down the HRS/CYCLES button and depress the START/STOP key. In run-in mode the unit will not force reverse. This has been found useful because some minor binding problems can be solved by simply running the unit. However, there is the danger that major binding problems will cause the fuse to blow. During run-in the display should read:

AAA RUN-IN F NNN

where AAA= Kneepot angle in degrees, NNN= Measured force,
If the measured force value falls into range depress the START/STOP button twice to resume normal force check mode. If there are no binding problems and the unit runs from -5 to 110 degrees or vice versa the microcontroller will set bit 3 of EE_CAL_STATUS, stop the unit and display:

CAL COMPLETE

***Note: Remove the jumper from the CTE connections on the main PCB.
(16) Install the bottom cover (refer to section 3.3.1.2).

4.3.6.2 Notes

5. Service Level IV

5.1 Who this involves

Individuals wishing to perform maintenance at Service Level IV must be trained by Danninger Medical service technicians or other technician approved by Danninger as a Service Trainer.

Service at this level includes trouble-shooting the PC boards at component level, replacing firmware, etc.

For further information contact Danninger Medical Technology, Inc. at 614-276-8267 or 800-*****.

6. Warranty Information

Danninger Medical Technology, Inc. ("Danninger") warrants to the original purchaser ("Buyer") of this Danninger 460 (the "Unit") that the Unit will be free from defects in material or workmanship for a period of one year from the date of original purchase. This warranty does not obligate Danninger to repair or replace a Unit not defective at the time of purchase which is damaged by accident, abuse, misuse, misapplication, or unauthorized repairs or alterations. Danninger makes no other warranties, express or implied (including, without limitation, merchantability, fitness for particular purpose, or against infringement of any patent), except as expressly provided herein.

If the Unit does not conform to this warranty, Danninger will at its option repair or replace the defective Unit. The remedy of repair or replacement is Buyer's sole and exclusive remedy and will satisfy all of Danninger's liabilities, whether based on contract, negligence, tort, product liability, strict liability, or otherwise. In no event shall Danninger be liable for incidental or consequential damages, nor shall its liability in connection with any defective unit exceed the sales price of such unit.

For this limited warranty to apply, Buyer must provide Danninger with written notice of a claimed defect within thirty days after its discovery, but not later than the expiration date of the warranty term. Within a reasonable time following receipt of such notice, Danninger will advise Buyer of the disposition of the Unit. Unless expressly authorized in writing, the defective Unit must be returned to Danninger for warranty coverage. Danninger reserves the right to inspect the Unit to determine whether the claimed defect is within the coverage of this limited warranty.

7. Returning the unit to the factory

Any unit being returned to the factory for repair or replacement must have a Return Authorization Number to be properly received. To obtain an RA# call Danninger's Customer Service Department. When you make the call you should have the following information available:

Company Name

Address the unit should be shipped to after repairs are completed

The unit Model number

The unit serial number

As much information as possible about the problem

Phone number for the person who will authorize a Purchase Order for the repair costs

The unit should be packed in its original carton with all internal packing in place. Any unit received in packaging not deemed safe for return shipment of the unit will be charged for a replacement carton.